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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,057	10/05/2000	Edwin W. Ades	99,017-B	7894

7590 04/13/2004

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,057	ADES ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2January2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Restriction, received 2January2004, is acknowledged. Applicants elect, with traverse, Invention II, claims 13-24, drawn to protein and method of use.

Applicant's election with traverse of is acknowledged. However, no arguments have been put forth. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-24 are pending. Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 13-24 are under consideration.

Specification

4. The disclosure is objected to because of the following informalities:

Page 4, line 4, "pnueumoniae" should be "pneumoniae"; line 10, "pnuemococcal" should be "pneumococcal"; line 25, the status of U.S. Pat. Appl. 08/222,179 is incorrect, Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim depends from a nonelected claim.

8. Claims 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is drawn to a protein "having a purity of $\geq$80% and substantially free from contaminant proteins and lipopolysaccharides". It is unclear what is the relationship of the percent purity and the "substantially free" requirement.

Dependent claims 15-19 do not clarify the indefiniteness.

9. Claims 20-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions which induce antibodies, does not reasonably provide enablement for the broad scope of the instant claims, i.e., protective vaccination of animals with any/all preparations of lipidated PsaA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of

experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – protection of animals against *S. pneumoniae* infection by administration of recombinantly produced, lipidated PsaA.

The state of the prior art provides insufficient guidance for the production of the claimed PsaA or protection administration. Therefore, there is a lack of predictability in the art for the claimed invention.

The amount of direction or guidance present in the instant specification is insufficient to support the broad scope of the instant claims, e.g., administration of any/all preparations of recombinantly produced lipidated PsaA resulting in protection of recipients against colonization with *S. pneumoniae* following intranasal administration.

The presence only working examples presented in the instant specification for administration of PsaA to animals is Example 3, pages 26-28. In this Example 3, there are four experimental administrations to mice. None of the administrations contain a description of the route of administration of the lipidated PsaA. Therefore, the examiner can not make an accurate assessment for either the presence or lack of support for nasal administration. The first experiment, page 26, line 23 to page 27, line 2, describes adult mice which were given DP2 and the titer of resultant antibodies was measured in the sera. The second experiment, page 27, lines 3-13, utilized two types of recombinant PsA, High Five (H5) and Sf9, given to adult mice. The sera from these mice were tested for antibodies to H5, Sf9, and native PsaA. The third experiment was a passive protection experiment in which infant animals, presumably mice, received sera from adult immunized mice. Following challenge with bacteria, 100% of infant mice receiving Sf9 antisera died at day 10, and 40% of mice receiving H5 sera died.

The fourth and last experiment, page 27, line 21 to page 28, line 6, involved immunization of adult and infant mice with Sf9 or H5 recombinant PsaA. All of the infant mice died following immunization with Sf9. All surviving mice were boosted with immunogen and challenged on day 21. 20% of infant animals receiving H5 were bacteremic. As stated in the specification "Adult data were inconclusive." Based upon the teachings in the specification one can conclude that: 1) Sf9 by itself kills infant mice, 2) H5 results in 20% of infant animals becoming bacteremic, and 3) neither Sf9 nor H5 produce conclusive protection in adult mice.

Thus, from the incomplete data of the only example in the specification, the quantity of experimentation necessary to fulfill the broad scope of the instant claims constitutes merely an invitation to experiment without a reasonable expectation of success

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

April 7, 2004